USSN: 10/698,348
Group Art Unit: 3736
Docket No. 151-P-11706US01

REMARKS

Claims 1 – 28 are pending in this application.

Claims 19 – 21 and 24 – 26 have been amended.

Claims 1—18 have been allowed.

Claims 19 – 28 have been rejected.

Claims 19, 20, 21, 24, 25 and 26 have been objected to.

Entry of Amendment

Entry of this amendment under the provisions of 37 CFR § 1.116, amendment after final, is respectfully requested.

Entry of this amendment under the provisions of 37 CFR § 1.116 (b) is requested because the amendment presents claims in better form for consideration on appeal by complying with matters of form, i.e., claim objections.

Further, entry of this amendment under the provisions of 37 CFR § 1.116 (c) is requested upon showing of good and sufficient reasons why the amendments are necessary and why the amendment were not presented earlier. The amendments are necessary because the amendments comply with matters of form raised by the Examiner. The amendments were not presented earlier because the matters of form were not noticed earlier and the matters of form were only made of record by the Examiner in the Office Action, made final, mailed September 13, 2006.

Amendments to the Claims

Claims 19 and 24 have been clarified by correcting typographical errors.

Claims 19 and 24 erroneously referred to "said vacuum source operating in conjunction with said vacuum source." The first reference to "vacuum source" should have referenced the structure interfacing between the vacuum source and the catheter lumen having reference in claim 19, line 14, and claim 24, line 13, respectively.

Accordingly, the term "vacuum source" has been amended to "structure". This amendment is supported by paragraph [31] of the specification and throughout the remainder of the specification. Additionally, claims 19 and 24 have been amended to correct a lack antecedent basis for "said baseline" in line 18 and 17, respectively. The term "said baseline" has been amended to read "a baseline", providing antecedent basis for "baseline." No new matter has been added.

Claim 24 has been further clarified by correcting an additional typographical error. Claim 24 establishes antecedent basis for a "restriction" between a first and a second chamber in line 2. However, the phrase "said lower esophageal sphincter" was used without antecedent basis in line 19. Accordingly, the phrase "said lower esophageal sphincter" has been amended to "said restriction" in line 19 for clarity and antecedent basis. This amendment is supported throughout the specification. No new matter has been added.

Claims 20 and 25 have been clarified by correcting typographical errors and an incorrect reference to a method step within an apparatus claim. The phrase "a baseline" was changed to "said baseline" in line 2 (of both claims 20 and 25). Proper antecedent basis for the word "baseline" is provided in claim 20, line 18, and claim 24, line 17. Additionally, the phrase "said pulling back step" has been amended in lines 2 – 3 (of both claims 20 and 25) to read "removing said catheter" to amend a reference to a method step to a timing requirement relative to a required function for the "means for determining" recited in lines 1 – 3 (of both claims 20 and 25). These amendments are supported in paragraph [32] of the specification and throughout the remainder of the specification. No new matter has been added.

Claims 21 and 26 have been clarified by correcting typographical errors. The phrase "comprising measuring a predetermined distance" has been amended in lines 1 – 2 (of both claims 21 and 26) to "comprising means for measuring a predetermined distance" in order to properly recite functional means for language and to avoid the recitation of a method step in an apparatus claim. These amendments are supported in paragraphs [41] and [42] of the specification. No new matter has been added.

Objections to the Claims

Claims 19, 20, 21, 24, 25 and 26 have been objected to because of informalities.

Claims 19 and 24 have been objected to due to the use of the phrase "said vacuum source operating in conjunction with said vacuum source" renders to the claim indefinite. Accordingly, claims 19 and 24 have been amended (claim 19, lines 14 – 15; claim 24, lines 13 – 14) to replace the phrase with the phrase "said structure operating in conjunction with said vacuum source" which is definite.

Claims 19 and 24 have been objected to due to the use of the phrase "said baseline" which lacks antecedent basis. Accordingly, claims 19 and 24 have been amended in lines 18 and 17, respectively, to change to phrase to "a baseline" thereby providing proper antecedent basis.

Claim 24 has been objected to due to the use of the phrase "said lower esophageal sphincter" which lacks antecedent basis. This phrase has been replaced by "said restriction" which does have antecedent basis in line 2.

Claims 20 and 25 have been objected to for use of the phrase "a baseline" in line 2 which conflicts with the phrase "a baseline" in claim 20, line 18, and claim 24, line 17. Accordingly, the phrase has been replaced by "said baseline" in line 2 of claims 20 and 25 reflecting proper antecedent basis.

Claims 20 and 25 have also been objected to for use of the phrase "said pulling back step" which lacks antecedent basis. Accordingly, the phrase has been replaced by the phrase "removing said catheter" which is a proper timing requirement relative to a required function of the "means for determining" recited in lines 1 – 3 of both claims 20 and 25.

Claims 21 and 26 have been objected to for use of the phrase "comprising measuring a predetermined distance" in lines 1 – 2 of both claims 21 and 26. Accordingly, the phrase has been replaced by the proper means plus function phrase "means for measuring a predetermined distance".

With the amendments to the claims described above, it is respectfully submitted that all of the stated informalities have been rectified. It is respectfully requested that the objections to claims 19, 20, 21, 24, 25 and 26 be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 1 – 28 over Kilcoyne et al '897, Silverstein et al '938, Higuma et al '708 and Sugrue et al '216

Claims 19 – 28 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,285,897 ("Kilcoyne et al '897"), U.S. Patent No. 5,247,938 ("Silverstein et al '938"), U.S. Patent 6,464,708 ("Higuma et al. '708") in view of U.S. Patent No. 5,433,216 ("Sugrue et al '216"). These rejections are respectfully traversed.

Kilcoyne et al '897 discloses the use of an endoscope to place a physiological monitor in the esophagus by using ligation (column 7, line 19 – 22). An endoscope is defined in the *American Heritage Diction, Fourth Edition,* Houghton Mifflin Co., 2000, on page 591, as "an instrument for examining visually the interior of a bodily canal" [emphasis added]. Alternately, Kilcoyne et al '897 discloses that the physiological monitor may be inserted via an esophagotomy or gastrotomy invasive surgical procedure. (column 7, lines 30 – 33). In either case, Kilcoyne et al '897 requires the use of a separate invasive procedure (endoscope or surgical procedure) in addition to a securing procedure to properly locate and anchor a capsule in a wall of the esophagus. Kilcoyne et al '897 does not show, disclose or suggest the use of any means other than the use of an endoscope or an invasive surgical procedure to position a physiological monitor in the esophagus.

By contrast, the structure required by the apparatus of claims 19 and 24 is considerably different resulting in a significantly advantageous result. Claims 19 and 24 require an apparatus for determining an esophageal location using (1) a catheter with a lumen (e.g., claim 19, lines 5 – 6); (2) a source of gas (e.g., claim 19, lines 9 – 10); (3) a pressure measurement means for measuring lumen pressure (e.g., claim 19, lines 11 –

12), (4) a vacuum source (e.g., claim 19, line 13), and (5) a structure anchoring a capsule to the wall of the esophagus (e.g., claim 19, lines 14 – 16) using the vacuum source (e.g., claim 19, lines 14 – 16). As stated in paragraph [15] of the specification, the point of the invention is to "take advantage of the already existing catheter...", thereby obviating the need for additional pieces of equipment.

Kilcoyne et al '897 does not show, disclose or suggest the structure recited in independent claims 19 and 24. Instead, Kilcoyne et al '897 teaches away from the presently claimed invention by explicitly reciting the use of other pieces of equipment, such as an endoscope or other invasive surgical procedure instead of a pressure sensor included in the catheter to determine a location within the esophagus. Kilcoyne et al '897 does not show, disclose or suggest the use of a pressure sensor for measuring the pressure of gas in the lumen of the catheter in the implantation procedure, thereby failing to meet element (3). Instead, any pressure sensor utilized in Kilcoyne et al '897 is part of a separate apparatus, e.g., the endoscope, that Kilcoyne et al '897 teaches is ultimately placed in the esophagus (column 5, lines 14 – 29). Likewise, Kilcoyne et al '897 does not show, disclose or suggest a gas source (element (2)), a vacuum source (element (4)), or anchoring the probe using the vacuum source (element (6)).

Silverstein et al '938 likewise discloses the use of an endoscope (column 5, line 40) to place a probe with a pressure sensor in the digestive tract (column 3, lines 5 – 17). Silverstein et al '938 does not show, disclose or suggest a catheter with a pressure sensor for use in inserting a probe in the esophagus without the use of other equipment, such as an endoscope, thereby failing to meet element (3) above. Silverstein et al '938 instead teaches away from using the pressure sensor to determine the location where the probe is to be placed by teaching the use of the endoscope – instead, as the examiner notes, the probe is intended to determine motility, or the extent to which something is capable of movement, within the body, thereby teaching away from determining a particular location within the esophagus by measuring pressure. Furthermore, Silverstein et al '938 does not show, disclose, or suggest a gas source within a catheter (element (2)). Thus,

Silverstein et al '938 does not show, disclose or suggest the required structural elements of claims 19 and 24.

Higuma et al '708 likewise specifically requires the use of an endoscope (claim 1, line 1; column 3, lines 21 – 26; Figures 34 – 36; and throughout the specification). Higuma et al '708 does not show, disclose or suggest a pressure sensor for measuring lumen pressure attached to a catheter, thereby failing to meet element (3) above. Likewise, Higuma et al '708 does not show, disclose or suggest a vacuum source (element (4)), or anchoring a capsule using the vacuum source (element (6)). Instead, Higuma et al '708 discloses variceal ligation (column 1, line 10), which means anchoring an object by tying an object down using a filament or thread. Higuma et al '708 teaches away from the present invention by requiring an endoscope, and requiring ligation. Higuma et al '708 does not show, disclose or suggest the required structural elements of claims 19 and 24.

Sugrue et al '216 discloses a pressure sensor on a catheter based on a "balloon like tonometric catheter membrane" (column 13, line 59). Sugrue et al '216 consistently refers to a pressure sensor based in a balloon in the drawings and throughout the specification. By contrast, claims 19 and 24 require measuring a lumen pressure (element (3)), not the pressure in a balloon. The difference is substantial. As illustrated in Sugrue et al '216, Figure 7, the inflated balloon entirely obstructs the passageway in which it is positioned. By contrast, as illustrated in Figure 2 of the present invention, a pressure sensor based on lumen pressure does not obstruct the passageway in which it is positioned. Particularly in the gastrointestinal tract, having the ability to measure pressure without entirely obstructing the passageway may have significant safety implications. A blocked gastrointestinal tract may inhibit the ability of the patient to breathe, or block the passage of food or waste. Claims 19 and 24 of the present invention avoids the risk by requiring measuring the pressure in the lumen of the catheter, rather than requiring the use of a balloon, which will tend to block the passageway in which it is positioned. Sugrue et al '216 does not show, disclose or suggest the required structural elements of claims 19 and 24.

Thus, it can be seen that none of the cited art includes the element of a pressure sensor based on the measurement of lumen pressure. Claims 19 and 24 require "pressure measurement means for measuring a lumen pressure of said gas in said lumen" (see claim 19, lines 11 – 12; claim 24, lines 10 – 11). It is respectfully submitted that the rejection of claims 19 and 24 is improper and should be withdrawn.

Even though the cited art does not show, disclose or suggest all of the elements of claims 19 and 24, even if the cited art did show, disclose or suggest all of the elements of claims 19 and 24, there is nothing in any of the prior art cited by the examiner to show, disclose or suggest combining one piece of art with another. Silverstein et al '938, first in time among the cited art, discloses an apparatus for determining esophageal motility. Sugrue et al '216 discloses an apparatus for determining intra-abdominal pressure. Kilcoyne et al '897 discloses an apparatus for placing a remote monitoring sensor using ligation. Higuma et al '708, last in time, discloses an apparatus for performing ligation. There is nothing in Sugrue et al' 216 to suggest the desirability of combining certain elements of Sugrue et al '216 with certain elements of Silverstein et al '938 – the purpose of Sugrue et al '216 was to measure pressure within the esophagus, and there is no suggestion in Sugrue et al '216 of using pressure measurement to determine location within the esophagus. On the contrary, Sugrue et al '216 states that "in general, the system can be used to monitor whether or not the various sphincters throughout the body are working to seal off chambers by monitoring, e.g., pressures upon either side of various sphincters." Thus, Sugrue et al '216 has no reason to show, disclose or suggest using a pressure sensor to help in the attachment of a capsule in a particular place. This is in spite of the fact that Silverstein et al '938 preceded Sugrue et al '216 in time, and Sugrue et al had constructive notice of the ability to anchor a capsule on a wall of the esophagus.

The citation of Kilcoyne et al '897 and Higuma et al '708 serve to further illustrate that the combination of elements of claims 19 and 24 were not obvious to one of ordinary skill in the art. Silverstein et al '938 discloses a vacuum source, and attaching a capsule to a wall using the vacuum source. Sugrue et al '216 discloses using a catheter

with a pressure sensor and a gas source. If, for the sake of argument, it were conceded that there is no difference between a balloon pressure sensor and a lumen pressure sensor, and it were conceded that Sugrue et al '216 and Silverstein et al '938 included all of the elements of claims 19 and 24 (a conclusion we vigorously dispute), Kilcoyne et al '897 and Higuma et al '708 were both later in time than both Silverstein et al '938 and Sugrue et al '216, and thus Kilcoyne et al and Higuma et al had constructive notice of all of the elements of claims 19 and 24. But rather than combine the elements of Silverstein et al '938 and Sugrue et al '216, as the examiner states would have been obvious, Kilcoyne et al and Higuma et al persisted in using an endoscope, thereby requiring an additional piece of equipment than was necessary, did not include a pressure sensor on the catheter, and resorted to ligation, which, because it involves tying the capsule to the wall, is a much more involved process than simply applying suction. As has been established above, neither Kilcoyne et al '897 nor Higuma et al '708 include all of the elements of claims 19 and 24.

Thus, though all of the elements of claims 19 and 24 were readily available to Kilcoyne et al '897 and Higuma et al '708, neither Kilcoyne et al '897 nor Higuma et al '708 combined those elements, therefore making clear that the combination was not obvious to those of ordinary skill in the art. It is emphasized that we do not concede that a balloon pressure sensor and a lumen pressure sensor are the same, and that the above argument involved that concession for the sake of making the point that a combination of the elements of claims 19 and 24 is obvious to one of ordinary skill in the art. It is respectfully submitted that the rejection of claims 19 and 24 is inappropriate and should be withdrawn.

Thus, all of the required structural elements of claims 19 and 24 do not exist in Silverstein et al '938, Sugrue et al '216, Kilcoyne et al '897 and Higuma et al '708. None of these sources show, disclose or suggest a pressure sensor on a catheter based on measuring the lumen pressure of the lumen. Further, even if Silverstein et al '938, Sugrue et al '216, Kilcoyne et al '897, and Higuma et al '708 did have all of the elements of claims 19 and 24, it would not have been obvious to one skilled in the art to combine

those elements. Kilcoyne et al '897 and Higuma et al '708 had every opportunity to combine the allegedly identical elements and did not. Thus, it is respectfully submitted that the rejection of claims 19 and 24 under 35 U.S.C. § 103(a) is improper and should be withdrawn.

Claims 20 – 23 and 25 – 28 are dependent on claims 19 and 24, respectively, and therefore contain all of the limitations of claims 19 and 24, respectively. Because the rejections of claims 19 and 24 under 35 U.S.C. § 103(a) are improper, it is respectfully submitted that the rejection of claims 20 – 23 and 25 – 28 are improper and should be withdrawn.

Claims 21, 22, 26 and 27 over Kilcoyne et al '897, Silverstein et al '938, Higuma et al '708, Sugrue et al '216 and Bombeck, IV '470

Claims 21, 22, 26 and 27 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kilcoyne et al '897, Silverstein et al. '938, Higuma et al. '708 and Sugrue et al '216 as applied to claims 19 and 24 above, and further in view of U.S. Patent No. 4,981,470 ("Bombeck, IV '470"). These rejections are respectfully traversed.

As has been established above, neither Kilcoyne et al '897, nor Silverstein et al '938, nor Higuma et al '708, nor Sugrue et al '216, include the element of a means for measuring the lumen pressure of a lumen, as required in claims 19 and 24 on which claims 21, 22, 26 and 27 depend. The above arguments related to Kilcoyne et al '897, Silverstein et al '938, Higuma et al '708, and Sugrue et al '216 are hereby incorporated herein by references.

Like Sugrue et al '216, Bombeck IV '470 discloses the use of a "balloon inflation pressure sensor" (column 4, lines 22 – 23). Thus, Bombeck IV '470 in light of Kilcoyne et al '897, Silverstein et al '938, Higuma et al '708 and Sugrue et al '216, still does not include all of the elements of claims 19 and 24, and thus cannot possibly include all of the required structural elements of claims 21 in light of 19, 22 in light of 19, 26 in light of 24 and 27 in light of 24. Claims 19 and 24 require an apparatus for determining an esophageal location using (1) a catheter with a lumen (e.g., claim 19, lines 5 – 6); (2) a

source of gas (e.g., claim 19, lines 9 – 10); (3) a pressure measurement means for measuring lumen pressure (e.g., claim 19, lines 11 – 12), (4) a vacuum source (e.g., claim 19, line 13), and (5) a structure anchoring a capsule to the wall of the esophagus (e.g., claim 19, lines 14 – 16) using the vacuum source (e.g., claim 19, lines 14 – 16).

It is respectfully submitted that the rejection of claims 21, 22, 26 and 27 under 35 U.S.C. § 103(a) is improper and should be withdrawn.

Allowable Subject Matter

Applicant appreciates the indication of allowance of claims 1 – 18.

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Summary

In view of the amendments and arguments presented, claims 1 – 28 should be allowable, this application should be in condition for allowance and a notice to that effect is earnestly solicited.

Respectfully Submitted,

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